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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/965,738	09/27/2001	Timothy J. O'Brien	022438.43865	3856

28172 7590 02/15/2006

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EXAMINER

NICKOL, GARY B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/965,738	<b>Applicant(s)</b> O'BRIEN ET AL.	
	<b>Examiner</b> Gary B. Nickol Ph.D.	<b>Art Unit</b> 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 October 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 5-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5,6,10 and 11 is/are rejected.
- 7) ☒ Claim(s) 1-3 and 7-9 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Re: O'Brien *et al.*

Date of priority: 09-27-2001

### DETAILED ACTION

The Election filed 10-11-2005 in response to the Office Action of 07-13-2005 is acknowledged and has been entered.

Applicant's election with traverse of Group III claims 1-12 is acknowledged. Applicants have further elected SEQ ID NO:150 as the multiple repeat domain in Claim 1, part b. The traversal is on the ground(s) that a search and examination of all of the inventions would not impose a serious burden on the examiner. This is not found persuasive. MPEP 802.01 provides that restriction is proper between inventions that are independent or distinct. Here, the inventions of the various groups are distinct for the reasons set forth in the Action mailed 07-13-2005. Further, although the inventions are classified somewhat similarly, the classification of subject matter is merely one indication of the burdensome nature of the search involved. The literature search, particularly relevant in this art, is not coextensive and is much more important in evaluating the burden of search. Different searches and issues are involved in the examination of each group.

Applicants further argue (Response, page 7) that "with respect to the requirement to elect a single species for examination on the merits", Claim 1, part b does not include a genus species relationship. This argument has been carefully considered but is not found persuasive because no **species** requirement was required. The restriction was to a multitude of distinct CA125

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polypeptide molecules including the requirement that applicants choose one sequence identifier corresponding to one multiple repeat domain. Applicants elected SEQ ID NO:150 as the multiple repeat domain. Thus, the search (and examination) will extend solely to a polypeptide comprising the amino acid sequence order of SEQ ID NO:299 (amino acids 1-1637), SEQ ID NO:150, and SEQ ID NO:300 in said order. It is further noted that applicants assert that a CA125 molecule can include a variety of repeat domains in a single molecule. Applicants point to SEQ ID NO:162 (amino acids 1-11,721) as an example. Thus, as evidenced by applicant's statement, there are hundreds of different possible combinations of potential CA125 molecules.

Furthermore, as applicants note (Response, page 8) the amino acids that constitute the repeat domains are not all the same. They can vary by as much as 18%. This represents a high burden of search because the number of repeat domains, as well as the chemical constituency within any one CA125 molecule, may differ.

For these reasons the restriction requirement is deemed to be proper and is therefore made FINAL.

Claims 1-3, and 5-11 are pending and are currently under consideration.

### *Specification*

The amendment filed 10-11-05 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure (see paragraph 20). 35 U.S.C. 132(a) states that no

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amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

In another aspect of the present invention, the repeat domain comprises 156 amino acid repeat units which comprise epitope binding sites. The epitope binding sites are located “at least in part” in the C-enclosure at amino acids #59-79 (marked C-C) in SEQ ID NO.: 150 in Figure 5.

The introduction of “at least in part” appears to broaden the scope of possible epitope binding sites. Applicant is required to cancel the new matter in the reply to this Office Action.

Alternatively, applicant is invited to provide sufficient written support for the limitation indicated above. See MPEP 714.02 and 2163.06

The abstract of the disclosure is objected to because it appears to exceed 150 words in length. Further, the content of the abstract is objected to because it should not refer to purported merits or speculative applications of the invention.

Correction is required. See MPEP § 608.01(b).

The specification is further objected to on page 19, line 18 for improper disclosure of amino acid sequences without a respective sequence identifier, i.e. a SEQ ID NOs:. Hence, the disclosure fails to comply with the requirements of 37 CFR 1.821 through 1.825. In the absence of a sequence identifier for each sequence, Applicant must provide a computer readable form (CRF) copy of the sequence listing, an initial or substitute paper copy of the sequence listing, as well as any amendment directing its entry into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new

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matter, as required by 37 CFR 1.821(e-f) or 1.825(b) or 1.825(d). *Failure to supply the appropriate sequences identification numbers in response to this action will be considered non-responsive.*

The specification is further objected to because it contains an embedded hyperlink and/or other form of browser-executable code (i.e., see paragraph 0079). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

### ***Information Disclosure Statement***

Although considered, reference II of the IDS filed December 2, 2004 is improper because it includes a hyperlink. The referenced sequence should also include the proper accession number and date of publication.

### ***Claim Objections***

Claim 1, part b is objected to for referring to “non-elected” subject matter. The elected multiple repeat domain was solely drawn to SEQ ID NO:150 (see response filed 10/11/2005, page 6) which is not mentioned in Claim 1.

Claim 5 is also objected to for referring to non-elected subject matter as claimed in Claim 1, part b.

Claims 7-9 are objected to for reciting, “Figure 5C” as there is no Figure 5C.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 recites the limitation "repeat domain" in Claim 1. There is insufficient antecedent basis for this limitation in the claim. Amending the claim to recite "multiple repeat domain" can obviate this rejection

Claim 10 recites the limitation "transmembrane domain" in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "transmembrane" in Claim 1. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 6 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation of epitope binding sites that are located "at least in part" in the C-enclosure has no clear support in the specification and the claims as originally filed. The introduction of "at least in part" appears to broaden the scope of possible epitope binding sites. Applicant is required to cancel the new matter in the response

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to this Office Action. Alternatively, applicant is invited to provide sufficient written support for the "limitation" indicated above. See MPEP 714.02 and 2163.06

Conclusion: Any claims not mentioned above are objected to as being dependent from a non-allowable claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary B. Nickol Ph.D. whose telephone number is 571-272-0835. The examiner can normally be reached on M-Th, 8:30-5:30; alternate Fri., 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gary B. Nickol Ph.D.  
Primary Examiner  
Art Unit 1642

**GARY B. NICKOL, PH.D.**  
**PRIMARY EXAMINER**

GBN

